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COMMITTEE PRINT

OFFERED BY MR. BROWN OF OHIO

At the end of the bill, add the following:

TITLE X—AFFORDABLE PHARMACEUTICALS

Subtitle A—Greater Access to Affordable Pharmaceuticals

SEC. 1001. PATENT CERTIFICATION.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B), by striking clause (iii) and inserting the following:

"(iii)(I) If the applicant made a certification described in paragraph (2)(A)(vii)(IV) and—

"(aa) no action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; and

"(bb) the applicant does not bring an action for declaratory judgment authorized in subclause (II) before the expiration of the 60-

day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received;

the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received, provided none of the conditions for denial of approval in paragraph (4) apply.

"(II) With respect to an applicant who made a certification described in paragraph (2)(A)(vii)(IV), if an action referred to in item (aa) of subclause (I) is brought before the expiration of the period described in such item, or if the applicant brings an action for declaratory judgment of invalidity or noninfringement of such patent (which action is hereby authorized) before the expiration of the period described in item (bb) of such subclause, the approval shall, provided none of the conditions for denial of approval in paragraph (4) apply, be made effective in accordance with the following:

"(aa) If the action is an action referred to in subclause (I)(aa), and neither the holder of the approved application nor the owner of the patent seek a preliminary injunction prohibiting the applicant from engaging in the commercial

manufacture or sale (or both) of the drug, the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received.

"(bb) If the action is an action referred to in subclause (I)(aa), and such a preliminary injunction is sought and the court denies the motion, the approval shall be made effective on the date on which the court denies the injunction.

"(cc) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent is invalid or was not infringed, the approval shall be made effective on the date of the decision of the court.

"(dd) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent was infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code."; and

(2) by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively, and inserting after subparagraph (B) the following subparagraph:

"(C) With respect to a civil action described in subparagraph (B)(iii)(II):

"(i) Each of the parties shall reasonably cooperate in expediting the action.

"(ii) If the notice under paragraph (2)(B)(ii) contains an address for the receipt of expedited notification of such an action, the plaintiff shall, on the date the complaint is filed in the court, simultaneously cause a notification of such action to be delivered to such address by the next business day.

"(iii) An action for a declaratory judgment authorized in such subparagraph may not be brought by the applicant until the expiration of 45 days after the date the notice provided under paragraph (2)(B)(ii) was received, except that if information on the patent involved has been published under subsection (c)(2) for at least one year after the date on which the application under this subsection was filed in relation to the listed drug involved, the applicant may immediately bring such an action for declaratory judgment.

"(iv) Any such action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business.".

(b) NEW DRUG APPLICATIONS.—Section 505(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)) is amended by striking subparagraph (C) and inserting the following:

"(C)(i)(I) If the applicant made a certification described in subsection (b)(2)(A)(iv) and—

"(aa) no action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under subsection (b)(3)(B) was received; and

"(bb) the applicant does not bring an action for declaratory judgment authorized in subclause (II) before the expiration of the 60-day period beginning on the date on which the notice provided under subsection (b)(3)(B) was received;

the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under subsection (b)(3)(B) was received, provided that none of the conditions for refusal of approval in subsection (d) apply.

"(II) With respect to an applicant who made a certification described in subsection (b)(2)(A)(iv), if

an action referred to in item (aa) of subclause (I) is brought before the expiration of the period described in such item, or if the applicant brings an action for declaratory judgment of invalidity or noninfringement of such patent (which action is hereby authorized) before the expiration of the period described in item (bb) of such subclause, the approval shall, provided none of the conditions for refusal of approval in subsection (d) apply, be made effective in accordance with the following:

"(aa) If the action is an action referred to in subclause (I)(aa), and neither the holder of the approved application nor the owner of the patent seek a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale (or both) of the drug, the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under subsection (b)(3)(B) was received.

"(bb) If the action is an action referred to in subclause (I)(aa), and such a preliminary injunction is sought and the court denies the motion, the approval shall be made effective on the date on which the court denies the injunction.

"(cc) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent is invalid or was not infringed, the approval shall be made effective on the date of the decision of the court.

"(dd) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent was infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

"(ii) With respect to a civil action described in clause (i)(II):

"(I) Each of the parties shall reasonably cooperate in expediting the action.

"(II) If the notice under subsection (b)(3)(B) contains an address for the receipt of expedited notification of such an action, the plaintiff shall, on the date the complaint is filed in the court, simultaneously cause a notification of such action to be delivered to such address by the next business day.

"(III) An action for a declaratory judgment authorized in such clause may not be brought by the applicant until the expiration of

45 days after the date the notice provided under subsection (b)(3)(B) was received, except that if information on the patent involved has been published under paragraph (2) for at least one year after the date on which the application was filed in relation to the drug involved, the applicant may immediately bring such an action for declaratory judgment.

"(IV) Any such action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business.".

(c) EFFECTIVE DATE.—The amendments made by this section shall not apply to an application submitted under section 505(b)(1) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) before June 7, 2002.

Subtitle B—Notification of Agreements Affecting the Sale or Marketing of Generic Drugs

SEC. 1011. DEFINITIONS.

In this subtitle:

(1) AGREEMENT.—The term "agreement" means an agreement under section 1 of the Sherman

Act (15 U.S.C. 1) or section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(2) ANTITRUST LAWS.—The term "antitrust laws" has the same meaning as in section 1 of the Clayton Act (15 U.S.C. 12), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(3) ANDA.—The term "ANDA" means an Abbreviated New Drug Application, as defined under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(4) BRAND NAME DRUG COMPANY.—The term "brand name drug company" means a person engaged in the manufacture or marketing of a drug approved under section 505(b) of the Federal Food, Drug and Cosmetic Act.

(5) COMMISSION.—The term "Commission" means the Federal Trade Commission.

(6) FDA.—The term "FDA" means the United States Food and Drug Administration.

(7) GENERIC DRUG.—The term "generic drug" means a product that is the subject of an ANDA.

(8) GENERIC DRUG APPLICANT.—The term "generic drug applicant" means a person who has

filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(9) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

SEC. 1012. NOTIFICATION OF AGREEMENTS AFFECTING THE SALE OR MARKETING OF GENERIC DRUGS.

A brand name drug company and a generic drug applicant that enter into an agreement regarding the sale or manufacture of a generic drug that the Secretary has determined is the therapeutic equivalent of a brand name drug that is manufactured or marketed by that brand name drug company, or for which the generic drug applicant seeks such a determination of therapeutic equivalence, and which agreement could have the effect of limiting the research, development, manufacture, marketing, or selling of a generic drug that has been or could be approved for sale by the FDA pursuant to an ANDA, shall file with the Commission and the Secretary the text of the agreement, an explanation of the purpose and scope of the agreement, and an explanation of whether the agreement could delay, restrain, limit, or in any way interfere with the production, manufacture, or sale of the generic version of the drug in question.

SEC. 1013. FILING DEADLINES.

Any notice, agreement, or other material required to be filed under section 1012 shall be filed with the Commission and the Secretary not later than 10 business days after the date the agreement is executed.

SEC. 1014. ENFORCEMENT.

(a) CIVIL FINE.—Any person, or any officer, director, or partner thereof, who fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than $20,000 for each day during which such person is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any person, or any officer, director, partner, agent, or employee thereof, fails to comply with the notification requirement under section 1012 of this subtitle, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Commission or the Assistant Attorney General.

SEC. 1015. RULEMAKING.

The Commission, in consultation with the Secretary, and with the concurrence of the Assistant Attorney Gen-

eral and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this subtitle—

(1) may require that the notice described in section 1012 of this subtitle be in such form and contain such documentary material and information relevant to the agreement as is necessary and appropriate to enable the Commission and the Assistant Attorney General to determine whether such agreement may violate the antitrust laws;

(2) may define the terms used in this subtitle;

(3) may exempt classes of persons or agreements from the requirements of this subtitle; and

(4) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this subtitle.

SEC. 1016. EFFECTIVE DATES.

this subtitle shall take effect 90 days after the date of enactment of this Act.